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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,693	10/14/2004	Masayuki Amagai	4439-4026	9184
27123	7590	04/04/2006	EXAMINER	
MORGAN & FINNEGAN, L.L.P.			SINGH, ANOOP KUMAR	
3 WORLD FINANCIAL CENTER			ART UNIT	
NEW YORK, NY 10281-2101			PAPER NUMBER	

1632

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/511,693	Applicant(s) AMAGAI ET AL.	
	Examiner Anoop Singh	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Claims 1-41 are pending.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

The inventions listed, as group I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I, claims 1-41, drawn to a remedy to be used in gene therapy comprising an immunosuppressive agent and a gene responsible for pemphigus and a method of treating said genetic disease.

Group II, claims 1-41, drawn to a remedy to be used in gene therapy comprising an immunosuppressive agent and a gene responsible for recessive genetic epidermolysis bullosa hereditaria dystrophica and a method of treating said genetic disease.

Group III, claims 1-41, drawn to a remedy to be used in gene therapy comprising an immunosuppressive agent and a gene responsible for junctional epidermolysis hereditaria bullosa and a method of treating said genetic disease.

Group IV, claims 1-41, drawn to a remedy to be used in gene therapy comprising an immunosuppressive agent and a gene responsible for hemidesmosome epidermolysis bullosa hereditaria or ichthyosis congenita and a method of treating said genetic disease.

The inventions listed as Groups I do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

3. The technical feature linking Group I-IV is a composition for gene therapy directed towards a genetic disorder comprising an immunosuppressive agent and a gene responsible for the genetic disease. Fang et al (Human Gene therapy, 1995, 6(8), 1039-1044) teach co administration of immunosuppressive agent cyclosporine A and blood clotting factor IX expressing adenoviral for the treatment of hemophilia B.

Therefore, the instant technical feature does not contribute over prior art. Additionally, The inventions of groups I-IV are patentably distinct, each from other because they are drawn to methods that have distinct steps, mode of action, require separate composition for practice and produce different results. The methods of group I-IV require administration distinct and different gene for the treatment of genetic disorders. The composition, mode of action and method step of each groups are distinct and different. Thus, searching for a method using different and distinct composition and different method steps will not be coextensive in the patent and non-patent literature.

Each disclosed species are directed to distinct and different goal, which comprises the use of a distinct immunosuppressive agent and gene in order to treat distinct genetic disorder. Thus, it follows from the preceding analysis that the claimed inventions listed as group I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons set forth above.

4. A search and examination of more than one invention as defined above would unduly burden the office. Each of the inventions requires a different search of the art and concerns separate considerations of patentability. For example, the subject matter of many of the inventions is not largely co-extensive as the inventions are related to distinct method and compositions. Therefore, restriction as defined above is proper.

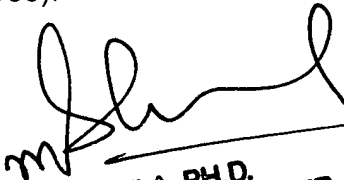
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anoop Singh whose telephone number is (571) 272-3306. The examiner can normally be reached on 8:30AM-5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272- 0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Anoop Singh, Ph.D.
Examiner, AU 1632


RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER